REMARKS

Claims 1 – 9 are currently pending and under examination.

Claims 1 and 4 have been amended *supra* to reflect that the RIAA and IAA are in therapeutically effective amounts. Support for such amendment may be found at, for example paragraphs [0023 & 0024] of the specification as filed. The Applicants aver that the amendment does not add new matter and respectfully request entry of the claims as amended.

I. CLAIM REJECTIONS UNDER 35 USC § 102(e)

Claims 1-3 and 8 stand rejected under 35 USC § 102(e) as being anticipated by Shahlal et al. (US 6,583,322). The Office states that Shahlal et al. disclose compositions comprising a reduced isoalpha acid (RIAA) and isoalpah acid (IAA) in "FIG.1; FIG.2; column 1, lines 14-24 and 60-63; and column 4, lines 2-25." The Office further alleges that "[i]t is disclosed that compositions therein which are mixtures of DHIA and IAA remained clear liquids at all ratios between about 1 and 99%, and comprise at least 0.1% of the composition. See column 18, lines 15-45." Applicants respectfully traverse for at least the following reasons.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. Specifically, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates." See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d at 1346; 51 USPQ2d 1943 (Fed. Cir. 1999) (internal citations deleted); See also MPEP 2131.03 (I).

Applicants submit that the range disclosed in Shahlal et al. does not fall within the ratios presently claimed and, therefore, Shahlal et al. cannot be an anticipatory reference.

FIG.1 in Shahlal et al. is only a "depiction of the structural formulas of cis and trans IA and DHIA" as described in the figure description in col. 14, lines 30-31. FIG.2 in Shahlal et al. is also a "depiction of the structural formulas of cis and trans THIA and HHIA" as described in col. 14, lines 32-33. Neither of these figures teaches or suggests that the structures are in a mixture; nor do they disclose any ratios or ranges of a mixture (if any).

In column 1, lines 14-24, Shahlal et al. generally describe IA, DHIA, THIA and HHIA and their analogs. They make no reference to any ratios or ranges of a mixture of IA and DHIA nor do they reference that any such ratio has antiinflammatory properties.

In column 1, lines 60-63, again Shahlal et al. make no reference to any ratios or ranges of a mixture of IA and DHIA. By stating that "[i]n these commercial preparations, the hop acids, and particularly 30% IA and 35% DHIA, as potassium slats at pH 10 or above in water, act as co-solvents for themselves" (emphasis added), Shahlal et al. make a reference to the lines above where they wrote that "IA is sold as a 30% solution of its potassium salt at a pH of about 10 in water. DHIA is sold as a 35% solution of its potassium salt in water at pH of about 10.5 and above, . . ." See col. 1, lines 49-52. Therefore, the phrase "30% IA and 35% DHIA" if read within its context (col. 1, lines 49-63) means that each of these preparation act as its own co-solvent at pH 10 or above.

In column 4, lines 2-25, Shahlal et al. make no reference to any therapeutically effective anti-inflammatory ratios or ranges of a mixture IA and DHIA when they write "[t]he objects of this disclosure are . . . to provide . . . [n]on-precipitating mixtures of DHIA and/or HHIA solutions with added IA and THIA."

In column 18, lines 15-45, Shahlal et al. make no reference to a ratio or range of a mixture of IA and DHIA that falls within the ratios presently claimed. Table 5-1, shows no mixing of IA and DHIA. Only in lines 36-38, Shahlal et al. make a general statement that "[m]ixtures of the DHIA and THIA and/or IA were compatible and remained clear liquids at all ratios between 1 and 99%." Although the "ratios between 1 and 99%" may cover the claimed ratios of 'RIAA (i.e., dihydroiso alpha acids) and IAA of about 3:1 to about 1:10', Shahlal ratios do not fall within the claimed ratios, nor do they have any anti-inflammatory properties and, therefore, cannot anticipate them.

Applicants further note that Shahlal et al is directed to composition having a high trans to cis ratio of isomers. The Applicants maintain that Shahlal teaches that the high trans ratio is important to the properties of non-precipitating, non-cloudy solutions (e.g., beer). Shahlal does not teach that the high trans ratio of isomers imparts any anti-inflammatory properties. This is important in that it is well recognized that even slight changes in orientation, crystalline or enantomeric structure can impart different properties. One need only look to coal versus a diamond to realize that while both are the same substance (carbon) their properties are vastly different due to their structure. Applicants maintain that Shahlal fails to anticipate the claims as amended since Shahlal does not teach anti-inflammatory compositions and methods.

Accordingly, Applicants submit that because the claimed ranges of RIAA and IAA have anti-inflammatory properties and are narrower than the ranges disclosed in Shahlal et al, claims 1-3 and 8 do not read on Shahlal et al. and are not anticipated by that reference. As such Applicants respectfully request that this rejection be withdrawn.

II. CLAIM REJECTIONS UNDER 35 USC § 103(a)

Claims 1-9 stand rejected under 35 USC § 103(a) as being unpatentable over Kuhrts (US 2004/0137096, herein after "Kuhrts").

The Office contends that "Kuhrts teaches a pharmaceutical composition comprising hops extract consisting of iso-alpha acids (IAA), and reduced iso-alpha acids (RIAA) such as . . . dihydroiso-humulone, . . . and combinations thereof. It is also disclosed that iso-alpha acids which are combinations of reduced isoalpha acid (RIAA) and isoalpha acid (IAA) will be present in an amount of 0.05% to 10% by weight in the hops extract." Office Action, page 4.

The Office acknowledges that "Kuhrts does not expressly teach the ratio of reduced isoalpha acid:isoalpha acidas about 3:1 to about 1:10, in the composition. Kuhrts does not expressly teach that the composition contains at least 0.1% of RIAA and IAA individually." Office Action, page 5. Nevertheless, the Office concludes that "[i]t would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid employed in the

composition of Kuhrts, to obtain a desired effect such as reducing inflammation." Office Action, page 5. Applicants respectfully traverse.

Applicants submit that they have unexpectedly discovered that compositions of reduced isoalpha acids (i.e., dihydro isoalpha acids) and isoalpha acids, when combined in certain amounts and ratios, have synergistic anti-inflammatory effects. See the entire application as filed and, for example, the title and abstract and Example 4. Accordingly, the claims reflect the finding of synergism. Kuhrts does not teach or suggest the element of "synergy" as claimed or taught by the present invention.

The Examiner, at page 7 of the Action, states that no synergy was noted for a ratio of RIAA and IAA, for example 1, wherein RIAA and IAA individually comprises at least 0.1% of the composition. The Applicants respectfully maintain that the Examiner is in error.

Applicants describe in their application that "synergy was noted for all RIAA:IAA combinations, albeit at different segments of the dose-response curves." See Example 4 of the application as filed on page 31, paragraph [0104] to page 32. This unexpected finding showed that while RIAA and IAA could act synergistically over a wide range of ratios and concentrations as shown in Figures 4A-H of the specification, they could also act additively or even antagonistically at certain other concentrations. See Figures 4A-H for tabulated CI (Combination Index) values and the specification on pages 30-31, paragraph [0100], which defines CI values of <1, $=1$, and >1 to indicate synergism, additivity and antagonism, respectively. The Examiner's attention is directed to Figure 4E which specifically demonstrates synergy wherein the RIAA and IAA each comprise at least 0.1% of the composition (see shaded area).

Thus, in view of the present specification, the synergistic property of a given combination of RIAA and IAA was shown to be unpredictable. In KSR, the Supreme Court reaffirmed that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 82 USPQ2d at 1395 1395-97 (2007); MPEP § 2141 guidelines for determining obviousness. However, as described above, by discovering synergism between the compounds claimed, Applicants have shown more than predictable results.

Furthermore, as described in Example 4 of the application and shown in Figures 4A-H, Applicants not only have discovered specific ratios in which RIAA and IAAs act synergistically (which is an effect greater than the expected sum of the additive effect of each compound taken separately), but they have also discovered to an unobvious extent that one must avoid the ratios at which the mixture of RIAA and IAA could act antagonistically.

Therefore, in view of the information disclosed in the present specification and the claims, Applicants submit that at the time of filing of the application, a skilled artisan who was familiar with the teachings of Kuhrts could not have distinguished between the additive or antagonistic and beneficially synergistic interactions of the compounds presently claimed. Accordingly, the skilled artisan would not have had a reasonable expectation of success in combining the compounds of Kuhrts or optimizing parameters to arrive at the presently claimed ratios. As such, Applicants respectfully submit that the invention as claimed is unobvious or Kurhrts and respectfully request withdrawal of the 35 USC § 103(a) rejection.

III. DOUBLE PATENTING REJECTION

Claims 1-7 stand provisionally rejected under the doctrine of obviousness-type double patenting as claiming the similar invention as that of claims 4-7 of copending Application 10/789,814 (Applicants Ref. No. 068911- 0075).

The Applicants accept the Examiner's determination and hereby provide a terminal disclaimer linking the two cited cases.

IV. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 1-9 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, The Examiner is requested to call Applicants' agent at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including October 29, 2009 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectively submitted,

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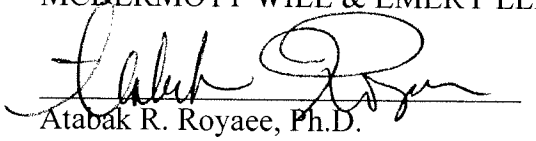

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